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Application No. 09/784,721

Attorney Docket No. 2000P19709

## REMARKS

Claims 1-11 are pending in this application, with claims 7 and 11 being amended by this response. Claims 7 and 11 are formally amended in accordance with the comments of the Examiner to correct a typographical error and provide antecedent basis for all terms. No new matter is added by these amendments.

### Objection to Claim 11

Claim 11 is objected to for certain informalities. Claim 11 has been amended in accordance with the comments of the Examiner to correct its claim dependency. In view of the amendment to claim 11, it is respectfully submitted that this objection is satisfied and should be withdrawn.

### Rejection of Claims 1-7 under 35 USC § 102(e)

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnhill et al., (U.S. Patent No. 6,306,087).

The present claimed invention describes a system for the automatic evaluation and quality control of medical point of care laboratory measurement data. The system includes a point of care measuring device disposed at a facility of a physician. The device obtains point of care laboratory measurement data. The system also includes a central expert system disposed remote from the location of the treating physician. A data link, selected from the group consisting of a data line and a data network, connects the central expert system to the point of care measuring device. The central expert system also includes access to a data bank. The data bank contains up-to-date medical knowledge and patient data. The data bank is accessible by the treating physician via the data link. The data bank functions as a virtual laboratory data collection and diagnostic system. The central expert system acts on the point of care laboratory measurement data with the up-to-date medical knowledge and patient data to make an

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evaluation available to the treating physician based on the point of care laboratory measurement data.

Barnhill et al. describe a simultaneous multi access reasoning technology system. The system utilizes both existing knowledge and implicit information that can be numerically extracted from training data to provide a method and apparatus for diagnosing disease and treating a patient. The system also receives patient data from another location, analyzes the data in a trained neural network, produces a diagnostic value, and optionally transmits the diagnostic value to another location. However, Barnhill et al. neither disclose nor suggest "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data." Contrary to the assertions made in the Office Action, Barnhill et al. actually disclose at Col. 7, line 66 to Col. 8, line 16, patient data being introduced to a neural network which eventually provides "formulation of a diagnosis or prognosis; transmission of the diagnosis to a remote location, optionally the location which send the original patient data set or the office of a health care provider." The diagnosis and prognosis only yield a name for what is ailing the patient and the likelihood of recovery from the disease. The claimed evaluation made available to the treating physician, on the other hand, as a result of networking with storage systems containing up-to-date medical knowledge and with electronic data banks for patient data, also provides therapy concepts and background knowledge (see page 5). Barnhill et al. neither disclose nor suggest, "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data" as in the present claimed invention.

The applicant also respectfully disagrees with the assertion made in the Office Action that Barnhill et al. disclose that an "expert system is connected online to a central laboratory for automatically reporting back a listing to said treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of said point of care laboratory measurement data does not produce a definitive diagnosis" as in claim 3 of

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the present claimed invention. Rather, Barnhill et al. in col. 13, lines 44-60 disclose the training of a neural network and "avoids the bias created by a dominant predictive variable" by excluding it from the first analysis. Thus Barnhill et al. neither disclose nor suggest, "automatically reporting back a listing...of secondary examinations available...if an initial evaluation...of said point of care laboratory measurement data does not produces a definitive diagnosis" as in the present claimed invention.

Applicant further respectfully disagrees with the assertion that Barnhill et al. disclose, "the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of care laboratory measurement data by using the results of the secondary examinations" as in claim 4 of the present invention. Rather, Barnhill et al. in Col 13, lines 44-60 disclose using a first set of biomarkers for one diagnostic index and combining them with a second set of biomarkers from another diagnostic index to get a final diagnostic index. This is to "avoid the bias created by a dominant predictive variable when training a network." This is unlike the present claimed invention, which re-evaluates data using secondary examinations when the system was unable to provide a definitive diagnosis. Thus, Barnhill et al. neither disclose nor suggest, "the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of care laboratory measurement data by using the results of the secondary examinations" as in claim 4 of the present invention.

Applicant also respectfully disagrees with the assertion made in the Office Action that Barnhill et al. disclose "a request to the point of care is automatically made for providing a sample for the central laboratory" as in claim 5 of the present invention. Rather, Barnhill et al. in Col. 13, lines 44-60 disclose using a first set of biomarkers for one diagnostic index and combining them with a second set of biomarkers from another diagnostic index to get a final diagnostic index. This is to "avoid the bias created by a dominant predictive variable when training a network." Thus, Barnhill et al. neither disclose nor suggest, "a request to the point of care is automatically made for providing a sample for the central laboratory" as in claim 5 of the present invention.

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Applicant further respectfully disagrees with the assertion that Barnhill et al. disclose, "expert system includes a data bank containing up-to-date medical knowledge and patient data and acts on said point of care laboratory measurement data using said medical knowledge and said patient data" as in claim 7 of the present claimed invention. Barnhill et al. in Col. 19, lines 19-26 disclose applying heuristic rules in combination with patient information such as family medical history and demographic information. However, Barnhill et al. neither disclose nor suggest including "up-to-date medical knowledge" as in claim 7 of the present invention.

In view of the above remarks, it is respectfully submitted that Barnhill et al. provides no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 1. As claims 2-7 are dependent on claim 1, it is respectfully submitted that claims 2-7 are patentable for the same reasons as claim 1 and the additional reasons discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

## Rejection of Claims 8 and 9 under 35 USC § 103(a)

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al., (U.S. Patent No. 6,306,087) in view of Jachimowicz et al., (U.S. Patent No. 5,763,862).

Jachimowicz et al. describe a dual card smart card reader including a portable housing with a viewing aperture and a virtual image display positioned to provide an image at the aperture. However, Jachimowicz et al., similarly to Barnhill et al., neither disclose nor suggest "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data" as in the present claimed invention.

The applicant respectfully submits that there is no reason or motivation to combine Barnhill et al. with Jachimowicz et al. Barnhill et al. disclose a system that uses both existing knowledge and implicit information received from training data to

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provide a method and apparatus for diagnosing disease and treating a patient.

Jachimowicz et al. disclose a dual smart card reader and a virtual image display.

Barnhill et al. and Jachimowicz et al. are responsive to different problems and thus it is respectfully submitted that the combination of these references to produce the present claimed invention would not be obvious. Barnhill et al. deals with diagnosing and treating patients. Jachimowicz et al., on the other hand, deals with viewing information stored on a smart card.

Even if there was a motivation to combine these two references, the combination of the system by Barnhill et al. with the system disclosed by Jachimowicz et al. as suggested in the Rejection results in a system that stores diagnosis and treatment information regarding a patient on a smartcard and a user's ability to view the information. The combination of Barnhill et al. and Jachimowicz et al. neither discloses nor suggests "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data" as in the present claimed invention.

In view of the above remarks, and the remarks concerning Independent claim 1, it is respectfully submitted that Barnhill et al. and Jachimowicz et al. when taken alone or in combination provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 1. As claims 8-9 are dependent on claim 1, it is respectfully submitted that claims 8-9 are patentable for the same reasons as claim 1 discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

**Rejection of Claims 10 and 11 under 35 USC § 103(a)**

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al., (U.S. Patent No. 6,599,481) in view of Stevens et al.

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Stevens et al. describe a substrate, in the form of a partitioned label, removably attached to a container that can be linked electronically to the operating stations in a laboratory and/or removed and subsequently attached to a document or another container. However, Stevens et al., similarly to Barnhill et al., neither disclose nor suggest "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data" as in claim 1 of the present invention. As claims 10 and 11 are dependent on claim 1, claims 10 and 11 are patentable for the same reasons stated above with reference to claim 1.

Additionally, the applicant respectfully submits that there is no reason or motivation to combine Barnhill et al. with Stevens et al. Barnhill et al. disclose a system that uses both existing knowledge and implicit information received from training data to provide a method and apparatus for diagnosing disease and treating a patient. Stevens et al. disclose a means for providing electronic information onto or into substrates that are connected with a container used to collect specimens. Barnhill et al. and Stevens et al. are responsive to different problems and thus it is respectfully submitted that the combination of these references to produce the present claimed invention would not be obvious. Barnhill et al. deals with diagnosing and treating patients. Stevens, on the other hand, deals with electronically tracking specimens.

Even if there was a motivation to combine these two references, the combination of the system disclosed by Barnhill et al. with the apparatus disclosed by Stevens et al. as suggested in the Rejection results in a system that electronically tracks the diagnosis and treatment of patients. The combination of Barnhill et al. and Stevens et al. neither disclose nor suggest "a central expert system...acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data" as in claim 1 of the present invention.

In view of the above remarks, and the remarks concerning Independent claim 1, it is respectfully submitted that Barnhill et al. and Stevens et al. when taken alone or in

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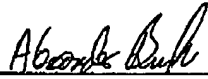
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combination, provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claim 1. As claims 10-11 are dependent on claim 1, it is respectfully submitted that claims 10-11 are patentable for the same reasons as claim 1 discussed above. It is thus further respectfully submitted that this rejection is satisfied and should be withdrawn.

New claims 12 -19 are hereby added by this amendment. New independent claim 12 is directed towards a central expert system for analyzing point of care laboratory measurement data. New independent claim 16 is directed towards a system for obtaining diagnoses and therapy concepts. No new subject matter is added by these claims and support for them can be found throughout the specification, and particularly on pages 2-4. It is respectfully submitted that the cited references when taken alone or in combination, provide no 35 USC 112 compliant enabling disclosure showing the features claimed in claims 12 and 16 for the same reasons discussed above with respect to claim 1. As claims 13-15 and 17-19 are dependent on claims 12 and 16, respectively, it is respectfully submitted that claims 13-15 and 17-19 are patentable for the same reasons as discussed above.

Having fully addressed the Examiner's rejections, it is believed that, in view of the preceding amendments and remarks, this application stands in condition for allowance. Accordingly then, reconsideration and allowance are respectfully solicited. If, however, the Examiner is of the opinion that such action cannot be taken, the Examiner is invited to contact the applicant's attorney at the phone number below, so that a mutually convenient date and time for a telephonic interview may be scheduled.

Respectfully submitted,  
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Date: June 14, 2005

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